QAPP GUIDELINES FOR
APPLIED RESEARCH PROJECTS

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following guidelines should be addressed as applicable.

TITLE PAGE

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DISTRIBUTION LIST - A distribution list shall be provided to facilitate the distribution of the most current version of the QAPP, project reports, and other project correspondence to all the principal project participants.

SECTION 1.0 PROJECT DESCRIPTION AND OBJECTIVES

1.1 A concise project definition or general overview shall be described. The purpose of study shall be clearly stated.

1.2 The process to be tested and the plant/facility at which the testing is to take place shall be described. The process should be broken down into its key steps and each step should be clearly defined. Use of flow diagrams is encouraged. All pertinent background information regarding the process itself or sludge characteristics to be tested should be discussed.

1.3 An overview of the project's sampling plan and a description of the key parameters which will be measured shall be presented.

1.4 Project objectives shall be clearly stated and identified as primary or non-primary.

1.5 All project tasks shall be defined along with a project schedule, timeline, Gantt chart, or table indicating projected initiation and completion dates.

SECTION 2.0 PROJECT ORGANIZATION AND MANAGEMENT

2.1 Key points of contact for each organization involved in the project shall be identified. Use organization charts for clarity if needed. Any preferred communication pathways should be identified.

2.2 Responsibilities of all project participants and their relationship to other project participants shall be identified. Organizations/individuals responsible for planning, coordination, sample collection, sample custody, measurements (i.e., analytical, physical,

and process), data reduction, data validation, and report preparation shall be clearly identified. Qualifications and/or resumes should be provided for key personnel, such as project managers and the laboratory(s) and person(s) performing the microbiological analysis.

2.3 Any specialized training or certification should be identified if required (e.g., OSHA's confined space entry training would be necessary to install a flow meter in a sewer main or specialized training may be necessary to conduct some of the microbiological techniques involved in demonstrating equivalency). The procedure for which the specialized training/certification is necessary should be identified. Documentation verifying completion of (or proof of timely registration for) the training/certification involved in the identified procedure must be provided.

SECTION 3.0 EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided in detail.

3.2 All details of the experimental design and/or sampling strategy shall be included.

3.3 Sampling/monitoring points for all measurements (including locations and access points) shall be identified. Use of flow diagrams or maps to specify sampling/monitoring points is encouraged.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including quality control (QC) and reserve samples.

3.5 All measurements or parameters of interest (i.e., analytical [e.g., chemical, microbiological, assays], physical [e.g., temperature], and process [e.g., flow rate]) shall be identified for each sample. Project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 Evidence must be presented to demonstrate that the design/strategy is appropriate for meeting primary project objectives, i.e., a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

SECTION 4.0 SAMPLING PROCEDURES

4.1 Sample/Monitoring Data Collection:

a. Each sampling/monitoring procedure to be used shall be discussed or referenced.
b. If compositing, splitting, or subsampling samples, those procedures shall be described.
c. Any site preparation needed prior to sampling/monitoring shall be described.

d. Known site-specific factors that may affect sampling/monitoring procedures shall be described.
e. The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.
f. Whenever applicable, the method used to establish steady-state conditions shall be described (e.g., sampling port was flushed for a minimum of 30 seconds before collecting sample).
g. If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.

4.2 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.3 Containers used for sample collection, transport, and storage for each sample type shall be described with respect to type of container, cleaning procedures, and pretreatment, if any.

4.4 Sample Handling:
a. Procedures for transporting, and packing and shipping samples shall be described.
b. For samples requiring a split sample for either quality assurance (QA)/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (e.g., field versus lab).
c. Sample preservation methods (e.g., refrigeration, acidification, etc.), including specific reagents, equipment, and supplies required for sample preservation shall be described.
d. Holding time requirements shall be noted.

4.5 Sample Labeling and Management:
a. The method for labeling and uniquely identifying each sample shall be described.
b. Procedures to maintain chain-of-custody (e.g., custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained and to document essential information such as date and time of sample collection and amount of elapsed time between sampling and analysis.
c. Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0 TESTING AND MEASUREMENT PROTOCOLS

5.1 The analytical method to be used for each analyte or parameter of interest shall be described in detail and/or referenced. Detection limits for each method should be listed.

5.2 Standard or EPA-approved methods shall be referenced by number for easy identification. Any modifications to EPA-approved or similarly validated methods shall

be specified regardless of how small or insignificant they may seem.

5.3 For unproven methods, all steps to the method must be described in detail. Any verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

SECTION 6.0 QA/QC CHECKS

6.1 The QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy (matrix spikes), precision (agreement of replicate analyses), detection limits, and completeness for critical measurements. For each specified QA objective, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The QAPP shall list and define all QC checks and/or procedures (e.g., blanks, surrogates, positive and negative controls, etc.) used for the project, both field and laboratory. For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

6.4 If sampling/monitoring equipment is used to collect critical measurement data (i.e., used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

6.5 For measurements which require a calibrated system or piece of laboratory equipment, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 7.0 DATA HANDLING PROCEDURES

7.1 If data is to be collected by an outside source, the following data acquisition requirements shall be included in the QAPP.

a. The deliverables expected from each organization responsible for field and/or laboratory activities shall be listed.
b. The required format for the data should be specified (spreadsheet, tabular, etc.)
c. The reporting requirements (e.g., units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The following data management items shall be discussed.

a. The method and person or persons responsible for collection, organization, and data entry (if required) for chain-of-custody forms should be stated.

b. If laboratory bench sheet are to be used, the method and person or persons responsible for collection, organization, and data entry should be stated. An example bench sheet should be included.

c. Data storage and backup requirements for each organization shall be provided.

7.3 Data review/validation/verification procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized. Frequency of data review for QA/QC measures should be specified.

7.4 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized (e.g., arithmetic mean, geometric mean, etc.). All statistical analyses applied to the data must be specified. Treatment of values below the limit of detection (non-detects) should be stated.

7.5 Any interim reports and the final product document that will be prepared for the project shall be specified with respect to timing, content, person or persons, responsible for preparation and anticipated recipients.

SECTION 8.0 ASSESSMENTS/OVERSIGHT

8.1 The QAPP shall identify all scheduled audits (i.e., both technical system audits and performance evaluations) to be performed, who will perform these audits, and who will receive the audit reports. If audit checklists are to be used and example should be included.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed. The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0 REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.